Attachment 1 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, upon which the substantial equivalence determination is based.

Summary Information:

Applicant: Kapp Surgical Instrument Co., Inc.
4919 Warrensville Center Road
Warrensville Heights, Ohio 44128
Tel: (216) 587-4400
Fax: (216) 587-0411

Contact : Albert Santilli, President

Prepared: March 10, 2005

Device Identification:

Proprietary Name: Mondeal® RADIUS HO System

Common Name: Screw, Fixation, Bone and Plate, Fixation, Bone

Classification Name and Regulation: Plate, Fixation, Bone, Class II
21 CFR 888.3030, 87HRS

Predicate Device(s): Synthes (USA) Distal Radius Plate System (DRPS) and
Hand Innovations, Inc. Distal Radius Fracture Repair System

Device Description:

The Mondeal® Radius Hand Osteosynthesis System consists of titanium volar and dorsal plates with shapes and sizes designed for internal fixation of distal radius fractures and osteotomies, and screws of varying lengths from 8 to 38 mm and 2.7 or 3.0 mm in diameter, supplied non-sterile packaged together in either tempered plastic or stainless steel trays suitable for recommended steam sterilisation, and also individually for single implantable use. The plates include dorsal and volar "T" shaped right and left hand configurations.. Manual reusable surgical instruments are supplied to facilitate implantation

Indications for use:

The Mondeal® Radius Hand Osteosynthesis System is intended to be used for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect.

Substantial Equivalence:

KAPP Surgical Instrument Co., Inc. considers the Mondeal® RADIUS HO System to be substantially equivalent to the aforementioned predicate devices with regard to intended use, materials, biocompatibility, and overall performance characteristics in accordance with the following comparison summary.

Comparison to the Predicate Devices:

Attribute	Candidate Device	Predicate Devices	
Product Name	Mondeal® RADIUS HO System	Hand Innovation Distal Radius Fracture Repair	SYNTHES (USA) Radius Plate System
Use	Single Use, Permanent	Single Use, Permanent	Single Use, Permanent
Plate and Screw Material	Ti-6Al-4V ELI plates and screws	Ti-6Al-4V ELI plates pegs, and screws	Titanium alloy and titanium plates and screws
Sizes	2.7 mm x 8 – 32 mm 3.0 mm x 8 – 32 mm	2.5mm x 10 – 28 mm	1.8mm x 10 – 26 mm 2.4mm x 10 – 26 mm
Available configurations	Right and left volar and dorsal	Right and left volar and dorsal	Right and left volar and dorsal
Indications for use:	Intended for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspects	Intended for the fixation of fractures and osteotomies involving the distal radius	Intended for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspects
Recommended sterilisation method	Steam	Steam	Steam
Packaging	Tempered plastic and stainless steel trays intended for steam sterilisation including plate, screw, and hand tool (Class I) assortment, plates and screws also packaged individually, all non-sterile, intended for sterilisation by purchaser.	Tempered plastic and stainless steel trays intended for steam sterilisation including plate, screw, and hand tool (Class I) assortment, plates and screws also packaged individually, all non-sterile, intended for sterilisation by purchaser.	Stainless steel trays intended for steam sterilisation including plate, screw, and hand tool (Class I) assortment, all non-sterile, intended for sterilisation by purchaser.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 - 2005

Albert Santilli, Ph.D.
Kapp Surgical Instrument Co., Inc.
4919 Warrensville Center Road
Warrensville Heights, Ohio 44128

Re: K050655
Trade/Device Name: Mondeal® RADIUS HO System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 1, 2005
Received: July 5, 2005

Dear Dr. Santilli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

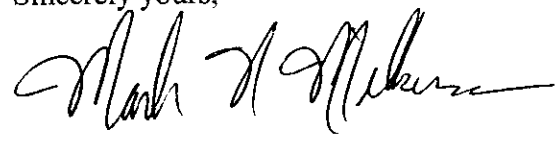
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

[510(k)] Number: K050655

Device Name: Mondeal® RADIUS HO System

Indications For Use:

The Mondeal® RADIUS HO System is intended to be used for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050655